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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/617,428
Filing Date: July 10, 2003
Appellant(s): SCHEWE ET AL.

Walter J. Steinkraus
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 7, 2007 appealing from the Office action mailed January 9, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,614,136	PEPIN et al.	3-1997
6,905,743	CHEN et al.	6-2005

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Pepin et al. (US Pat. 5,614,136) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 23: Pepin et al. teaches the claimed process of forming a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7). Pepin et al. specifically teaches that the varying the speed of the puller or drawing rate changes the volume of extruded material in a given length (6:5-24) which is essentially the rate of extrusion. Pepin et al. also teaches varying the pressure of the internal air/gas supply during processing to form different tubular segments (5:58-6:48). Pepin et al. does not specifically teach that different orientations (i.e. molecular orientation) occur during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional to the drawing/pulling rate. This is evidenced by Chen et al. which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45).

Furthermore it is submitted that by varying the draw rate of the material out of the extruder the speed of the material passing through the gap length inherently changes. Since the "cooling rate" within the gap depends upon the time the extruded tube is within the gap length, it is inherent that the "cooling rate" also changes at this point as the drawing rate changes.

Similarly, it the amount of air/gas that enters the gap length is directly proportional to the pressure of the gas. Therefore, the "cooling rate" would change by the amount of air/gas passed through the tube depending upon the pressure used to form each segment.

Regarding claims 24-25: Pepin et al. also teaches varying the drawing/pulling rate between at least two different value sets or profiles wherein the wall thickness varies including tapers or waist portions (Figs. 7 exhibits a repeating pattern between two different diameters and Fig. 2a for wall thickness variations). It is submitted that the high pulling speeds which would cause higher drawing and smaller diameters (i.e. at a constant extrusion rate) would experience higher shearing forces and thereby inherently have a higher degree of molecular orientation in these regions relative to the larger diameter regions.

Claims 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Pepin et al. (US Pat. 5,614,136) when taken with Chen et al. (US Pat. 6,905,743).

Regarding claim 43: Pepin et al. teaches the claimed process of forming a polymeric tube segment, comprising: extruding a polymeric tube (Fig. 6); drawing/pulling the tube through a cooling bath (Fig. 6); and altering/varying the drawing rate to change the dimensions in at least two regions or predetermined locations along the tube (3:9-60; 6:5-25, and Fig. 7). Pepin et al. also teaches varying the pressure of the internal air/gas supply during processing to form different tubular segments (5:58-6:48). Lastly, Pepin et al. teaches that process is carried out to "meet required operation and performance characteristics" of the tubular member (7:15-25), which would be inherently inclusive of yield and break strengths (i.e. elongation properties) of the final product. Pepin et al. does not specifically teach that different orientations (i.e. molecular orientation) occur during drawing. Nonetheless, it is inherent that axial/longitudinal molecular orientation is proportional is the drawing/pulling rate. This is evidenced by Chen et al.

which teaches that a high speed puller imparts a shearing force on a molten/deformable material thereby causing molecular orientation (5: 20-45). It is submitted that the high pulling speeds which would cause higher drawing and smaller diameters (i.e. at a constant extrusion rate) would experience higher shearing forces and thereby inherently have a higher degree of molecular orientation in these regions relative to the larger diameter regions.

Furthermore it is submitted that by varying the draw rate of the material out of the extruder the speed of the material passing through the gap length inherently changes. Since the "cooling rate" within the gap depends upon the time the extruded tube is within the gap length, it is inherent that the "cooling rate" also changes at this point as the drawing rate changes. Similarly, it the amount of air/gas that enters the gap length is directly proportional to the pressure of the gas. Therefore, the "cooling rate" would change by the amount of air/gas passed through the tube depending upon the pressure used to form each segment.

The examiner recognizes that all of the claimed effects and physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

Regarding claims 44-45: Again, the examiner recognizes that all of the claimed effects and physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients, process steps, and process conditions. Therefore, the claimed effects and physical properties would inherently be achieved by carrying out the

disclosed process. If it is applicants' position that this would not be the case: (1) evidence would need to be presented to support applicants' position; and (2) it would be the examiner's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects by carrying out only these process steps.

(10) Response to Argument

Appellant's argument essentially alleges that the applied prior art does not anticipate claims 23-25 and 43-45 because the examiner has disregarded critical recitations in the claims. The examiner disagrees with the argument and submits that the claims are met by the prior art as set forth in the Final Office action. The examiner submits that each and every claimed limitation is expressly or inherently met by the applied prior art.

As an initial matter, it is noted that the examiner and appellant appear to substantially agree on several facts regarding inherency and the general meaning of certain terms in the art:

a) On page 5 of the brief, appellant recites that "[f]or the purposes of this appeal applicant does not dispute the asserted inherency of different orientations occurring under at least some of the drawing rate changes. Accordingly, Chen et al. will not be discussed in detail." As provided in the rejection, the examiner agrees that the pulling process set forth by Pepin inherently orients the material differently at the different dimensional locations and that this fact is evidenced by Chen et al.

b) On page 6 of the brief, appellant provides a "background review" (page 6, line 1). In the review, appellant provides background showing what one having ordinary skill in the art would understand and know when discussing balloon catheters. In the review, it is made clear that cone portions, waist portions and a body portion

are parts of balloon catheters. The examiner agrees that balloon catheters have cone portions, waist portions and a body portion. Chen et al. provides additional supporting evidence in this regard. Figure 1 shows a tubular parison prior to being formed into a balloon device and Figure 2 shows the final form of the balloon device. It is noted that the device in Figure 2 has a body portion, cone portions, and waist portions.

FIG. 1

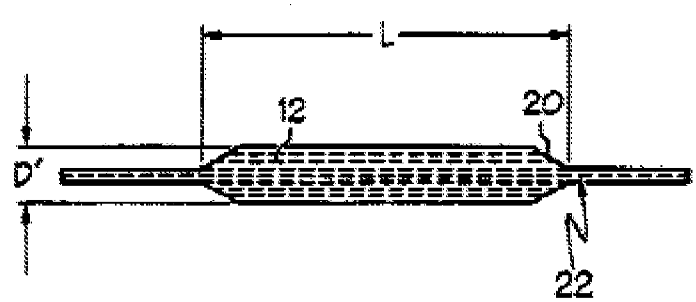

FIG. 2

c) Additionally, at the bottom of page 6 and continuing on the top of page 7 of the brief, appellant states: "A balloon starts out as an extruded tube, but at some

point...different regions are slated to become different parts of the balloon. This may occur by…intermediate processing of a tubing segment so that the tube has different dimensions.” The examiner agrees that processing of an extruded tubing segment to provide a tube having different dimensions is a way to slate the different parts of the balloon. The examiner submits that this is what Pepin et al. do, as will be explained in more detail below.

d) Further, in the instant disclosure, published as US 2005/0008806, it is stated that “…portions of balloon parisons will be slated to become the waist, cone or body. This is usually done inherently.” The examiner agrees that the slating process whereby the waist, cone or body portions are defined is an inherent process (i.e. no additional positive/manipulative steps are performed).

Regarding claim 23, appellant’s argument essentially alleges that the rejection fails to satisfy the claimed relationship directed to slating portions to form cone, waist and body portions of the balloon. This argument is not persuasive. The examiner submits that Pepin et al., in view of the foundational facts set forth above in bullets a) – d), quite reasonably teach each claimed limitation either expressly or inherently. Appellant argues that the examiner’s error begins with the preamble wherein the method pertains to a balloon parison not to a “polymeric tube segment”. This argument is not persuasive. While the examiner acknowledges that the term “polymeric tube segment” was employed in the final rejection as a representative term for rejecting a number of claims, the examiner submits that Pepin et al. expressly teach the method is applicable to and intended for balloon catheters:

“The present invention relates to guide, angiographic and diagnostic and <u>balloon dilation catheters</u> and method of manufacturing catheters. In particular, the present invention

includes a process for forming a dimensionally variable continuous tubular member for use in catheterization procedures." (col. 2, lines 26-31, emphasis added).

As can be understood from the discussion and Figures in bullets a) - d) above, the formation of a dimensionally variable tubular member for balloon dilation catheters meets the argued limitation.

Appellant cites (page 8 of the brief) col. 3, lines 31-35 from Pepin et al.:

"the present invention may be used to manufacture dimensionally variable tubular members for use in manufacturing catheter shafts, catheter tips, fuseless catheter systems, and other products where dimensionally varying characteristics are desirable"

Appellant concludes from this citation that Pepin et al. say nothing about forming balloons from the disclosed dimensionally variable tubing. This argument is not persuasive. As set forth above, Pepin et al. teach the applicability of their invention for balloon catheters at col. 2, lines 26-31. When col. 2, lines 26-31 and col. 3, lines 31-35 are taken together, the examiner submits one having ordinary skill would understand that balloon catheters are still intended and are not excluded by the citation at col. 3, lines 31-35.

Appellant argues that a review of Figure 7 from Pepin et al. and the pertinent citations explaining Figure 7 make it clear that this Figure has nothing whatsoever to do with a balloon parison. This argument is not persuasive. As an initial point, the examiner acknowledges and agrees that Figure 7 specifically exemplifies making a catheter tip 20. However, the examiner submits that this argument ignores the teaching at col. 2, lines 26-31 of Pepin et al. stating that the method is also intended for forming balloon catheters. The examiner also submits the argument ignores the knowledge and understanding one having ordinary skill in the art would employ, as set forth in bullets a)-d) above, when interpreting and applying the teaching of Pepin et al. The examiner submits that one having ordinary skill in the art, having the foundational

knowledge set forth in bullets a)-d) above and in view of the explicit statement by Pepin et al. at col. 2, lines 26-31, would clearly know and immediately envisage that the varying dimensions formed by Pepin et al., as exemplified in the Figures for a catheter tip, would also apply to the waist, cone and body portion of a balloon catheter. For example, looking at Figure 7 of Pepin et al., the examiner submits that one having ordinary skill would immediately understand and interpret Pepin et al. to teach that the cuts (80) need only be made in a different location to produce the explicitly recited balloon catheter of Pepin et al. instead of the exemplified catheter tip.

Regarding claim 24, appellant argues that the examiner's contentions regarding inherency are irrelevant since the slating relationship cannot be inherently met by Pepin et al. This argument is not persuasive. For the reasons set forth above, the examiner submits the slating relationship is met by Pepin et al. and that, accordingly, the examiner’s assertions are not irrelevant. Additionally, the examiner notes that the final rejection addresses the more specific relationship presented in the claim.

Regarding claim 43, appellant argues that Pepin et al. do not teach selecting the alteration of the drawing rate on the basis of elongation at yield properties of the extrusion as a choice criterion. This argument is not persuasive. The examiner notes that appellant does not dispute that Pepin et al. show a process for extruding polymeric material in which a drawing rate is altered to provide at lest two regions along the length thereof (last 2 lines of page 11 and first 2 lines of page 12 in the brief). Further, as is not disputed and as evidenced by Chen et al., the changes in drawing/pulling rate in Pepin et al. inherently yield different orientations of the material within the article at the different locations. The examiner notes and submits that this different orientation inherently yields different “longitudinal stabilization” properties (e.g. elongation at yield properties) as is also evidenced by Chen et al. at col. 5, lines 35-40.

Accordingly, the examiner submits that the choice to change the dimensions in Pepin et al. by adjusting the drawing/pulling rate, also changes the “longitudinal stabilization” properties (e.g. elongation at yield properties) of the article in the same locations the dimensions are changed.

Regarding claims 44 and 45, appellant argues that the examiner's contentions regarding inherency are irrelevant to the claims and that Pepin et al. do not teach or suggest selecting the elongation at yield properties of the different sections as claimed. This argument is not persuasive. For the reasons set forth above, the examiner submits the argued limitation is met by Pepin et al. and that, accordingly, the examiner’s assertions are not irrelevant. Additionally, the examiner notes that that the final rejection addresses the specific limitations set forth in the claims.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner’s answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Jeff Wollschlager/
Examiner, Art Unit 1791

Conferees:

/Jennifer Michener/
QAS, TC1700

/Christina Johnson/
Supervisory Patent Examiner, Art Unit 1791